K 110255

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APR - 4 2011

510(k) Summary

Submission Date:	13 January 2011
Submitter:	Sound Surgical Technologies LLC 357 South McCaslin Boulevard, Suite 100 Louisville, CO 80027
Submitter and Official Contact:	Mr. Stephen C. Smith Vice President of RA/QA Sound Surgical Technologies LLC 357 South McCaslin Boulevard, Suite 100 Louisville, CO 80027 +1 (720) 240-2970 SSmith@soundsurgical.com
Manufacturing Site:	Sound Surgical Technologies LLC 357 South McCaslin Boulevard, Suite 100 Louisville, CO 80027
Trade Name:	Sound Surgical Technologies LLC PowerX Lipo System
Common Name:	Power-Assisted Aspiration Cannula System
Classification Name:	System, Suction, Lipoplasty
Classification Regulation:	21 CFR §878.5040
Product Code:	MUU

Substantially Equivalent Devices:

Sound Model	*Predicate 510(k) Number*	*Predicate Manufacturer and Model*
Sound PowerX Lipo System	K012236	KMI Kolster Methods, Inc. Stars2000 Power Cannula

Device Description: The Sound Surgical Technologies LLC (Sound) PowerX Lipo System (PowerX) consists of three major components: (1) an electronic Controller with software, (2) an electronic Handpiece, and (3) a reusable, sterilizable Cannula. The Handpiece is connected to the Controller and to an independent aspiration source. The Controller sends electronic signals to the Handpiece and thereby controls the motion of the cannula that is fitted to the distal end of the Handpiece.

The Sound PowerX is a prescription device, and is intended for use by trained medical personnel.

Intended Use: The Sound Surgical PowerX Lipo System is intended for the removal of tissue or fluids from the body during general surgical procedures including suction lipoplasty for the purpose of aesthetic body contouring.

Technology Comparison: The Sound PowerX employs the same technological characteristics as the predicate device with a few minor differences:

Predicate Device	Sound PowerX Lipo System
Stepper motor in handpiece	Brushless DC motor in handpiece
Direct drive cannula	Motor/gearbox drive arrangement
Suction path through motor shaft	Suction path offset from motor axis
Graphical user interface	Seven-segment LED display user interface
Membrane switches/buttons	Rotary switches and knobs

Performance Testing:

Sterilization The Sound PowerX Controller is not sterilized or sterilizable, and therefore this section does not apply to the Controller.

The Sound PowerX Handpiece and Cannulae are not provided sterile, but are sterilized by the user prior to use. The sterilization of the Handpiece and Cannulae was validated in accordance with:

- *ISO 17665-1: 2006, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.*

Test results indicate that the Sound PowerX complies with the standard.

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Biocompatibility

The Sound PowerX Controller has no patient contact materials, and therefore this section does not apply to the Controller.

The Sound PowerX Handpiece and Cannulae have patient contact materials and are made from medical grade biocompatible materials.

Test results and analyses indicate that the Sound PowerX Handpiece and Cannulae materials comply in accordance with:

- *ISO 10993-1: 2003, Biological evaluation of medical devices – Part 1: Evaluation and testing.*

Software Testing

The Sound PowerX contains MODERATE level of concern software. Software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05; and*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*

Test results indicate that the Sound PowerX complies with its predetermined specification.

Electrical Safety

The Sound PowerX was tested for patient safety in accordance with:

- *IEC 60601-1:1988, Am1: 1991, Am2: 1995, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*
- *IEC 60601-1-8: 2006, Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Test results indicate that the Sound PowerX complies with the standards.

Electromagnetic Compatibility Testing

The Sound PowerX was tested for EMC in accordance with:

- *IEC 60601-1-2: 2007, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.*

Test results indicate that the Sound PowerX complies with the Standard.

Performance Testing – Bench	The Sound PowerX was tested for performance in accordance with its predetermined specifications as specified in *Section 11, Device Description – Performance Specifications*, of this submission. Test results indicate that the Sound PowerX complies with its predetermined specification.
Conclusion	Verification and validation activities were conducted to establish the performance and safety characteristics of the Sound PowerX. The results of these activities demonstrate that the Sound PowerX is safe and effective when used in accordance with its intended use and labeling. Therefore, the Sound PowerX is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sound Surgical Technologies LLC
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

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Re: K110255
Trade/Device Name: Sound Surgical Technologies LLC PowerX Lipo System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: March 18, 2011
Received: March 21, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 110255

Device Name: Sound Surgical Technologies LLC PowerX Lipo System

Indications for Use: The Sound Surgical Technologies LLC PowerX Lipo System is intended for the removal of tissue or fluids from the body during general surgical procedures including suction lipoplasty for the purpose of aesthetic body contouring.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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